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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

Date: March 11, 2011

SUBJECT: (RE-ISSUED) Health Effects Division (HED) Review of Agricultural Handler Exposure Task Force (AHETF) Monograph: Open Cab Ground Boom Application of Liquid Sprays

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THROUGH: David J. Miller, Chief 11.MAR.2011
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This memorandum presents the Health Effects Division review of the occupational handler exposure scenario monograph "Open Cab Ground Boom Applications of Liquid Sprays" submitted by the Agricultural Handler Exposure Task Force. It has been corrected to address transcription and typographic errors identified in the original publication (7/1/10). Additionally, references to "interim" dermal exposures have been removed. The exposure data are acceptable and recommended for use in applicable pesticide handler exposure and risk assessments.

Rec'd w/ RRC 3/15/2011

I. EXECUTIVE SUMMARY

This document represents the Health Effects Division (HED) review of the Agricultural Handler Exposure Task Force (AHETF) Monograph: Open Cab Ground Boom Application of Liquid Sprays (AHETF, 2009). HED confirms that the data meets study design benchmarks outlined in the AHETF Governing Document (AHETF, 2007) and is considered the most reliable data for assessing exposure and risk to individuals making ground boom applications of liquid spray solutions[1] while wearing the following personal protective equipment (PPE): long-sleeved shirts, long pants, shoes, socks, chemical-resistant gloves and no respirator[2]. This dataset supersedes the current dataset[3] used to assess exposure and risk for open cab ground boom applications.

Select summary statistics for the open cab ground boom liquid spray application scenario "unit exposures" are presented in Table 1 below, as well as the PHED value previously used for comparison.

Table 1. Unit Exposures (ug/lb ai handled): Open Cab Ground Boom Application of Liquid Sprays

Exposure Route	PHED	AHETF[a, b]		
	"Best Fit"	Geometric Mean	Arithmetic Mean[c]	95th Percentile[d]
Dermal	14	6.9	16.1	58.5
Inhalation	0.74	0.12	0.34	1.27

[a] Dermal unit exposures reflect default 50% adjustment of hand and face/neck measurements to account for potential exposure method collection inefficiencies. The average percent of dermal exposure representing the hands, face, and neck is 37.6%.
[b] Statistics are estimated using a variance component model accounting for correlation between measurements conducted within the same field study (i.e., measurements collected during the same time and at the same location). Additional model estimates (e.g., empirical and simple random sample assumptions) are described in Section III.
[c] Arithmetic Mean (AM) = GM * exp{0.5*((lnGSD)^2)}
[d] 95th percentile = GM * GSD^1.645

The following important points with respect to these data are noted:

- The AHETF data and associated unit exposures are considered superior to the existing open cab ground boom application of liquid sprays dataset (i.e., PHED data) and its "best fit" unit exposure. AHETF efforts represented a well-designed, concerted process to collect reliable, internally-consistent, and current exposure data in a way that takes advantage of and incorporates a more robust statistical design, better analytical methods, and improved data handling techniques.
- Dermal exposure results reflect the default 50% wash removal efficiency adjustment (i.e., a factor of 2X) used to correct hand and face/neck measurements when their contribution

[1] Additional data (5 monitored subjects in study AHE39) is available that suggests different (higher) exposures for groundboom applicators performing soil-incorporated applications and/or utilizing wettable powder formulations. Though the Agency will utilize the data outlined in this review for all types of groundboom applicator exposures, assessments of soil-incorporated groundboom applications or groundboom applications of wettable powder formulations may also utilize that additional, albeit limited, data.
[2] Adjustments to this dataset to represent alternative personal protective equipment (e.g., applying reduction or protection factors to reflect the addition or removal of protective clothing, gloves, respirators, etc.) are not included in this review.
[3] Pesticide Handlers Exposure Database (PHED) Scenario 13: Ground boom Application, Open Cab (Appl)

to overall exposure is 20% - 60%. Additional information or data on the efficiency of the hand wash and face/neck wipe methods may waive this default adjustment and modify the exposure results. Inhalation exposure results are final, as they are not subject to pending measurement method efficiency adjustments.

- The data is not applicable for assessment of exposure and risk to highly volatile pesticides (e.g., fumigants).

- The AHETF collected dermal and inhalation exposure measurements (n = 5) of participants applying liquid sprays mixed from wettable powder formulations as part of a soil incorporated, ground boom application. On average, these participants had higher exposures than participants using other sprayable formulations (e.g., liquid concentrates). Recorded observations of participant activity suggest the higher exposures were the result of clearing nozzles on spray booms that were repeatedly becoming clogged. The AHETF asserts that it is unclear whether the nozzles were getting clogged due to the use of the wettable powder formulation used in the field study or due to the fact that the pesticide application was being soil incorporated. In sum, it is not possible at this time to deduce the particular factors resulting in the higher exposures for these participants.

  Thus, the data potentially representing these two ground boom application "sub-scenarios" (Groundboom Applications of Wettable Powder Formulations and Soil-Incorporated Groundboom Applications) are not included in the AHETF open cab ground boom scenario at this time and are not part of the summary statistics presented in Table 1. The Agency may include this additional data to supplement the standard open cab groundboom applicator exposure assessments. Details for the participants making soil incorporated ground boom applications are in Table 3.

- Statistical analysis does not provide support for proportionality between dermal and inhalation exposure and the amount of active ingredient handled – a key assumption in the use of exposure data as "unit exposures". Despite this, HED will continue to use the exposure data in this format as a default condition given that the assumption of proportionality results in overestimates of exposure in standard HED occupational handler assessments. In light of this finding, however, HED will consider alternate uses of the open cab ground boom applicator exposure data in the future (e.g., exposure independent of the amount of active ingredient handled or normalized by an alternate exposure factor).

II. BACKGROUND

The AHETF is developing a compensable database representing worker exposure during major agricultural and non-agricultural handler scenarios. A scenario is defined as a pesticide handling task based on activity (e.g., application) and equipment type (e.g., open cab ground boom). Generally, AHETF scenarios represent individuals wearing long-sleeved shirts, long pants, shoes, socks and chemical-resistant gloves. An exception is the use of chemical-resistant headgear for overhead exposure (e.g., open cab airblast applications), for which cloth patches located inside and outside the headgear are used to measure head exposure.

In this case, the scenario is applications of liquid pesticide sprays with ground boom equipment by workers wearing long sleeve shirts, pants, shoes, socks, chemical-resistant gloves, and no respirator. The figures below (from AHETF, 2009) depict examples of ground boom applications for which the exposure data is applicable.

Figure 1: Open Cab Ground Boom Application – Field Crop

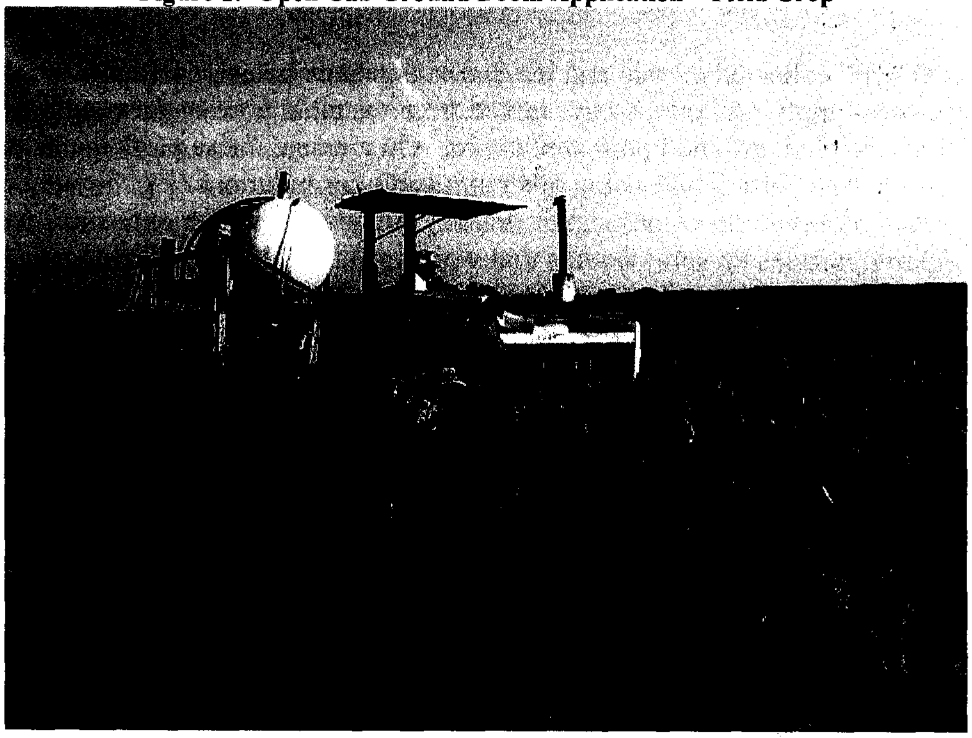
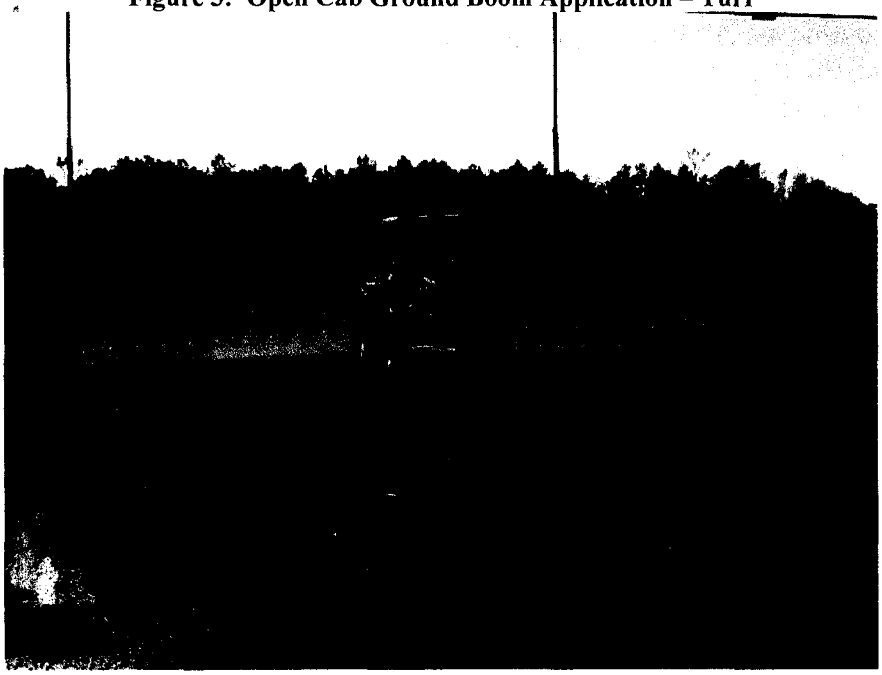


Figure 2: Open Cab Ground Boom Application - Orchard

Figure 3: Open Cab Ground Boom Application – Turf



Dermal and inhalation exposure monitoring was conducted for workers making ground boom applications and expressed, for use in exposure assessments, as "unit exposures". A "unit exposure" (UE) is defined as the expected external chemical exposure an individual may receive (i.e., "to-the-skin" or "in the breathing zone") per weight-unit chemical handled and is the default data format used in pesticide handler exposure assessments. Mathematically, unit exposures are expressed as "handler" exposure normalized by the amount active ingredient handled (AaiH) by participants in scenario-specific exposure studies (e.g., mg exposure/lb ai handled). These UEs are then used generically to model exposure for other chemicals having the same or different application rates.

Two major assumptions underlie the use of exposure data in this fashion. First, the expected external exposure is unrelated to the active ingredient in the pesticide formulation. That is, the physical characteristics of the pesticide formulation (e.g., formulation type – wettable powder, liquid concentrate, dry flowable, etc.) or the equipment type used to apply the pesticide influence exposure more than the specific pesticide active ingredient (Hackathorn and Eberhart, 1985). Thus, for example, exposure data for mixing and loading one chemical formulated as a wettable powder can be used to estimate exposure for another chemical formulated as a wettable powder. Second, dermal and inhalation exposure are assumed proportional to the amount of active ingredient handled. In other words, if one doubles the amount of pesticide handled, one doubles the exposure.

The AHETF developed criteria reviewed by HED and presented to the Human Studies Review Board (HSRB) for determining when a scenario is considered complete and operative. Outlined in the AHETF Governing Document (AHETF, 2007), the criteria can be briefly summarized as follows:

- The primary objective of the study design is to be 95% confident that key statistics of normalized dermal exposure are accurate within 3-fold. Specifically, the upper and lower 95% confidence limits should be no more than 3-fold higher or lower than the estimates for each the geometric mean, arithmetic mean, and 95th percentile dermal unit exposures. To meet this primary objective AHETF proposed an experimental design that provides a sufficient number of field trials and a sufficient number of monitored individuals. Note that this "fold relative accuracy" objective does not apply to normalized inhalation exposure, though estimates are provided for reference (see Table 4).

- A secondary objective is to evaluate the assumption of proportionality between exposure and AaiH in order to be able to use the AHETF data generically across application rates. To meet this objective, the AHETF proposed a log-log regression test to distinguish complete proportionality (slope = 1) from complete independence (slope = 0), with 80% statistical power, achieved when the width of the 95th confidence interval of the regression slope is 1.4 or less. Note, again, that this objective does not apply to normalized inhalation exposure; however the tests are performed for informational purposes.

- To achieve both the primary and secondary objectives described above, the AHETF developed a study design employing a 'cluster' strategy. Each cluster is defined by a region. Typically, these regions are defined by a few contiguous counties in a given state(s) within a US EPA growing region. For most handler scenarios a configuration of 5 regional clusters consisting of 5 participants is used to meet the objectives from a statistical sample size perspective. The 25 total participants and the conditions under which the worker handles the active ingredient are referred to as monitoring units (MUs). Within each cluster, the AHETF partitions the practical AaiH range handled by the participants in each cluster appropriate to a given scenario. In general, the strata of AaiH for any given scenario is commensurate with the assumptions HED uses in handler risk assessments with respect to acres treated (e.g., 200 acres treated for ground boom applications for an 8 hour work day).

III. RESULTS

The data for the open cab ground boom applicator scenario were collected prior to the development of the AHETF Governing Document which established the statistical benchmark objectives outlined above in Section II. Thus, this scenario is comprised of 29 MUs collected in 7 separate field studies[4], with no repeat sampling of the same individual:

- AHE18 (EPA MRID 47212806) – 2 MUs
- AHE20 (EPA MRID 47212808) – 1 MU
- AHE21 (EPA MRID 47212809) – 2 MUs
- AHE30 (EPA MRID 47309201) – 5 MUs
- AHE31 (EPA MRID 47309202) – 5 MUs
- AHE32 (EPA MRID 47309203) – 6 MUs
- AHE40 (EPA MRID 47309204) – 8 MUs

While the sampling in this scenario does not reflect the current AHETF standard 5X5 design, it does possess many of the other sampling strategies outlined in the AHETF Governing Document, such as:

- representing the diversity of equipment types commonly assessed in Agency open cab ground boom applicator exposure assessments;
- including a variety of open cab tractors (with and without windshields and/or canopies);
- including front- (AHE30) and rear-mounted spray booms (all other field studies);
- involving applications to a variety of crops located in 4 different states;
- remaining consistent with the range of acres expected to be treated by this kind of equipment; and
- meeting the statistical benchmark objectives.

Calculating Unit Exposures

Dermal exposure is measured using 100% cotton "whole body dosimeters" (WBD) underneath normal work clothing (i.e., long-sleeved shirt, long pants, socks and shoes), hand rinses (collected at the end of the day and during restroom and lunch breaks), and face/neck wipes. The WBD is sectioned and analyzed by body part (i.e. upper and lower arms, upper and lower legs,

[4] As previously mentioned, MUs from another study, AHE39, are outlined in this document but excluded from this scenario as they represent soil incorporated wettable powder finished sprays. Exposure from such uses fall under a different exposure pattern and will be assessed separately from this scenario.

etc.). All samples are adjusted as appropriate according to recovery results from field fortification samples. Total dermal exposure (e.g., milligrams active ingredient) is calculated by summing exposure across all body parts for each individual monitored. Dermal unit exposures (i.e., mg/lb ai handled) are then calculated by dividing the summed total exposure by the amount of active ingredient handled.

Inhalation exposure is measured using a personal air sampling pump and an OSHA Versatile Sampler (OVS) tube with a glass fiber filter and Chromosorb 102 solvent. The tube is attached to the worker's collar to continuously sample air from the breathing zone. Collected residue, per standard practice, is adjusted for recovery from field fortification samples. Inhalation exposures are calculated by adjusting the measured air concentration (i.e., ug/L) for a worker's breathing rate – assumed 8.3 liters per minutes (LPM; converted from 1.0 m^3/hr), representing sedentary activities such as driving a tractor (NAFTA, 1998) – and total work/monitoring time:

Inhalation Exposure (ug) = collected air residue (ug) x [breathing rate (L/min) ÷ average pump flow rate (L/min)]

Inhalation unit exposures (i.e., mg/lb ai handled) are calculated by dividing the inhalation exposure by the amount of ai handled by the individual study participant.

Dermal and Inhalation Exposure Results

A summary of the 29 MUs and their dermal and inhalation UEs for the open cab ground boom applicator exposure scenario are presented in Table 2 below. For dermal unit exposures, both the hand wash and face/neck method efficiency adjusted (MEA) data and non-adjusted (non-MEA) are presented. Because they are not included in derivation of the open cab ground boom applicator exposure, exposure information for the 5 respective MUs based on the application of the wettable powder formulation as a soil incorporated spray are presented separately in Table 3. More detailed MU-specific exposure data is presented in Attachment 1.

All field studies conducted by the AHETF include the recording of individual participant activities by field observers. For this scenario, the field notes include observations such as nozzle repair (with and without gloves), manually or mechanically raising or lowering spray booms, the participant's interaction with the spray rig and the mixing/loading activities. Minor activities such as the use of cell phones were also noted. Select field notes are included in each table to provide examples of "real world" events during open cab ground boom applications; reviewers can find all field notes in the specific field studies.

Table 2. Open Cab Ground Boom Application Scenario: MU Summary

AHETF Participant	State	Work/ Monitoring Time (hours)	Crop	Area Treated (acres)	Boom Swath Width (ft)	Tank Loads Sprayed (#)	AaiH (lbs)	Unit Exposure (ug/lb ai)		
								Dermal[a]		Inhalation[a]
								MEA[b]	Non-MEA	
AHE18-A1	OR	10.3	Grass grown for seed	250	60	16	299	2.4	1.7	0.0949

AHE18-A2	OR	5.0	Grass grown for seed	100	60	4	128	0.94	0.61	0.0231
AHE20-A1	GA	5.1	Peanuts	9.2	18	6	9.9	46.5	38.2	7.89
AHE21-A1	FL	5.4	Peanuts	4.5	6	6	5	17.8	14.5	2.21
AHE21-A2	FL	2.6	Peanuts	34	36	3	37.2	4.4	3.7	0.077
AHE30-A1	OR	3.4	Blueberry	12	5	5	25.4	2.7	1.8	0.0778
AHE30-A2	OR	6.2	Blackberry	21	5	6	46.8	61.1	32.5	0.149
AHE30-A3	OR	8.9	Apples	22	10	7	57	8.6	5.8	0.112
AHE30-A4	OR	10.5	Pears	35	10	7	70.2	214	109	0.0823
AHE30-A5	OR	10.5	Pears	53	10	5	91.2	14.2	8.2	0.106
AHE31-A1	CA	6.5	Olives	30	20	5	138	22.3	18.4	0.0538
AHE31-A2	CA	6.1	Citrus	38	20	5	155	3.3	2.7	0.0757
AHE31-A3	CA	8.0	Citrus	48	20	6	195	2.7	2.0	0.0296
AHE31-A4	CA	6.7	Citrus	28	20	7	113	14.6	10.8	0.106
AHE31-A5	CA	6.2	Citrus	24	20	6	97.7	6.9	6.5	0.0636
AHE32-A1	FL	3.7	Cabbage	33	63	1	36.4	14.7	11.7	0.502
AHE32-A2	FL	7.8	Turf	56	30	8	408	6.8	4.5	0.0317
AHE32-A3	FL	7.0	Turf	46	30	7	350	0.98	0.77	0.00851
AHE32-A4	GA	6.7	Turf	46	36	5	263	2.7	1.7	0.0682
AHE32-A5	GA	6.6	Turf	15	12	15	88.1	10.1	7.0	0.84
AHE32-A6	GA	5.0	Turf	20	34	3	132	3.5	2.5	0.341
AHE40-A1	GA	6.7	Peanuts	70	36	4	79	9.3	8.1	0.426
AHE40-A2	GA	6.8	Soybeans	71	30	6	121	5.7	5.0	0.106
AHE40-A3	GA	7.2	Soybeans	80	36	8	145	3.6	3.0	0.0916
AHE40-A4	GA	9.2	Soybeans	107	36	8	182	3.3	2.4	0.191
AHE40-A5	GA	10.8	Soybeans	120	36	9	206	6.3	5.1	0.258
AHE40-A6	GA	9.6	Soybeans	130	38	8	241	5.1	4.0	0.356
AHE40-A8	GA	7.6	Turf	60	36	3	438	1.3	1.0	0.0244
AHE40-A9	GA	8.3	Turf	70	36	4	501	1.3	0.86	0.0355

[a] See Attachment 1 – Table 1 for additional exposure details.
[b] Values reflect use of the 50% default adjustment for hands and face/neck measurements.

Select Field Notes

- AHE30-A1: Participant brushed against berry foliage and got wet. Used arms to move branches out of the way. Moisture soaked through to skin on both upper and lower body.
- AHE30-A2: Took gloves off to fix snap fitting for spray nozzle.
- AHE30-A3: Fixed nozzles 5 times with gloves on.
- AHE30-A4: Worker noticed leak on the back of the tank. Turned the valve the wrong way and got sprayed in the face from the hose. Wiped face with sleeve. Tightened the valve with gloved hand.
- AHE30-A5: Leaned against tractor tire various times whilst tank was being filled.
- AHE32-A1: Equipment breakdown - got finished spray on gloves.
- AHE32-A2: Participant felt spray drift on face.
- AHE32-A4: Used garden hose to rinse the foaming agent containers. Added foaming agent to a small tank.

Table 3. Summary of MUs for Open Cab Ground Boom Soil-incorporated Sprays using Wettable Powder formulations

AHETF Participant	State	Work/ Monitoring Time (hours)	Crop	Area Treated (acres)	Boom Swath Width (ft)	Tank Loads Sprayed (#)	AaiH (lbs)	Unit Exposure (ug/lb ai)	
								Dermal[a]	Inhalation
AHE39-A1	ID	10.7	Sweet Corn (bare soil)	35	11.7	7	138	73.39	0.203
AHE39-A2	ID	8.6	Sweet Corn (bare soil)	12	11.7	2.4	48	19.5	0.309

AHE39-A3	ID	9.1	Sweet Corn (bare soil)	15	11.3	3	59	391.69	0.259
AHE39-A4	ID	8.5	Sweet Corn (bare soil)	25	13.3	5	96	52.95	None
AHE39-A5	ID	8.3	Sweet Corn (bare soil)	17.5	13.3	3.5	69	59.67	0.364

[a] Values reflecting use of the 50% default adjustment for hands and face/neck measurements are not presented.

Select Field Notes

- AHE39-A2: Application stopped due to rainfall.
- AHE30-A5: Application stopped due to high winds.

Evaluation of Scenario Benchmark Objectives

The AHETF monograph details the extent to which the OCBG Application scenario meets the current AHETF scenario objectives. Note that though the data were not developed under current study design objectives outlined in the AHETF Governing Document, the AHETF analyzed the data as if it were subject to these guidelines. HED has independently confirmed the AHETF results (Sarkar, B., 6/25/10; D000000) and agrees that the objectives have been met for this scenario.

Primary Benchmark Objective: fold Relative Accuracy (fRA)

The primary benchmark objective for AHETF scenarios is for select statistics – the geometric mean (GM), the arithmetic mean (AM), and the 95th percentile (P95) – to be accurate within 3-fold with 95% confidence (i.e., "fold relative accuracy"). The AHETF analyzed the data using various statistical techniques to evaluate this benchmark. First, to characterize the unit exposures (also referred to as "normalized exposure"), AHETF demonstrated that dermal and inhalation UEs (unadjusted for residue method collection efficiencies) appear to be lognormally distributed as shown by the reasonably straight-line fits in the lognormal probability plots below.

Figure 4: Lognormal Probability Plot of Dermal Unit Exposures (AHETF, 2009; pg. 133)

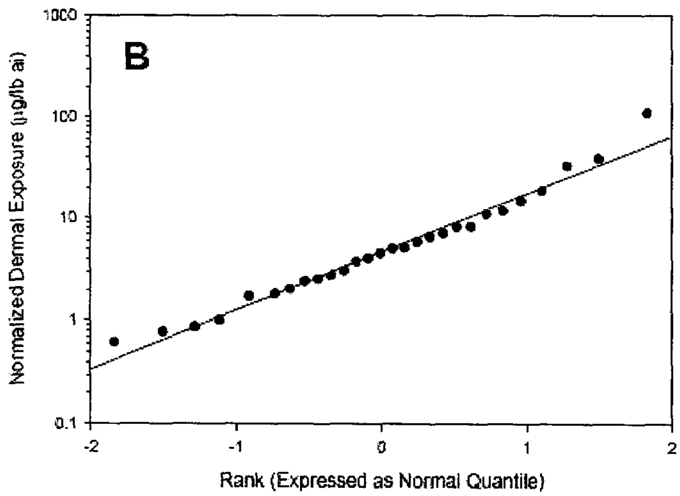
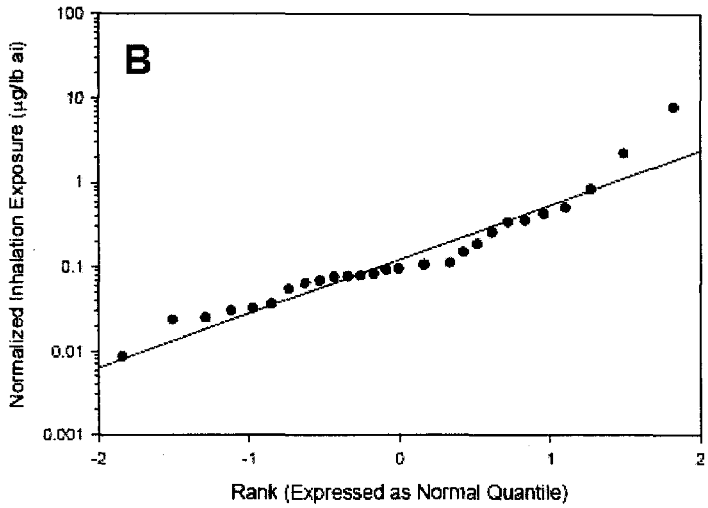


Figure 5: Lognormal Probability Plot of Inhalation Unit Exposures (AHETF, 2009; pg. 133)



Next, the AHETF calculated estimates of the GM, AM and P95 based on three variations of the data:

- Non-parametric empirical (i.e., ranked) estimates;
- Assuming a lognormal distribution and a simple random sample (SRS); and,
- Hierarchical variance component modeling to account for potential MU correlations.

The 95% confidence limits for each of these estimates were obtained by generating 10,000 parametric bootstrap samples. Then, the fRA for each was determined as the maximum of the two ratios of the statistical point estimates with their respective upper and lower 95% confidence limits. Table 5 below presents the results.

Table 4. Results of Primary Benchmark Analysis

	Dermal Exposure[a]			Inhalation Exposure		
Statistic	**Unit Exposure Estimate (ug/lb ai)**	**95% CI**	**fRA**	**Unit Exposure Estimate (ug/lb ai)**	**95% CI**	**fRA**
GM_S	6.4	3.4 – 14.4	2.2	0.12	0.07-0.21	1.7
GSD_S	3.49	2.48 – 5.26	1.5	4.13	2.85-5.96	1.5
GM_M	6.9	3.5 – 14.0	2.0	0.12	0.07 - 0.21	1.7
GSD_M	3.66	2.50 – 5.64	1.5	4.13	2.86 - 6.07	1.5
ICC	0.30	0.00 – 0.66	--	0.00	0.00 - 0.35	--
GM_S = geometric mean assuming SRS = "exp(average of 29 ln(UE)) values" GSD_S = geometric standard deviation assuming SRS = "exp(standard deviation of 29 ln(UE)) values" GM_M = variance component model-based geometric mean GSD_M = variance component model-based geometric standard deviation ICC = intra-cluster correlation						
AM_S	17.1	6.4 – 35.7	2.7	0.50	0.15 – 0.72	3.3
AM_U	13.9	6.7 – 37.9	2.7	0.34	0.16 – 0.73	2.2
AM_M	16.1	7.0 – 41.2	2.6	0.34	0.17 – 0.77	2.3
AM_S = average of 29 unit exposures AM_U = arithmetic mean based on $GM_S = GM_S*\exp\{0.5*((\ln GSD_S)^\wedge 2)\}$ AM_M = variance component model-based arithmetic mean = $GM_M * \exp\{0.5*((\ln GSD_M)^\wedge 2\}$						
$P95_S$	61.1	18.4 – 174.0	3.3	2.21	0.46 – 3.62	4.8
$P95_U$	49.8	22.0 – 144.2	2.9	1.27	0.56 – 2.81	2.3
$P95_M$	58.5	22.7 – 156.2	2.7	1.27	0.56 – 2.91	2.3
$P95_S = 95^{th}$ percentile (i.e., the 28th unit exposure out of 29 ranked in ascending order) $P95_U = 95^{th}$ percentile based on $GM_S = GM_S * GSD_S^\wedge 1.645$ $P95_M$ = variance component model-based 95^{th} percentile = $GM_M * GSD_M^\wedge 1.645$						
[a] Dermal exposure values reflect 50% default adjustment for hands and face/neck measurements.						

The benchmark of 3-fold accuracy for dermal unit exposures has been met for this scenario and the analysis confirmed independently by HED. Note, though not applicable to the benchmark, the fRA values for inhalation are sometimes higher than those for dermal exposure. Additionally, the primary objective was met regardless of whether the hand and face/neck samples were adjusted or not adjusted using HED's default 50% method efficiency correction.

Secondary Benchmark Objective – the relationship between exposure and AaiH

The secondary statistical benchmark of AHETF studies is to be able to distinguish, with 80% statistical power, complete proportionality from complete independence between exposure and amount of active ingredient handled. Recall that this benchmark applies only to dermal exposure, but analysis was performed on inhalation exposure as well and presented for informational purposes.

To evaluate the relationship for this scenario the AHETF performed regression analysis of ln(exposure) and ln(AaiH) to determine if the slope is not significantly different than 1 – providing support for a proportional relationship – or if the slope is not significantly different than 0 – providing support for an independent relationship. Since these data were collected prior to the study design outlined in the AHETF Governing Document (AHETF, 2007), which established the goal of 80% power, a post hoc power assessment was performed to see if this benchmark was achieved.

Both simple linear regression and mixed-effect regression were performed to evaluate the relationship between dermal exposure (unadjusted for exposure method collection inefficiencies) and AaiH. The resulting regression slopes and confidence intervals are summarized in Table 6 and in Figures 3 and 4 below. Note that a confidence interval width of 1.4 (or less) indicates at least 80% statistical power and those for simple linear regression are only valid if between-MU correlations are absent.

Table 5. Summary Results of log-log Regression Slopes

Regression Model	Dermal Exposure			Inhalation Exposure		
	Slope Estimate	95% CI	CI Width	Estimate	95% CI	Width
Simple Linear	0.34	-0.02 – 0.70	0.72	0.09	-0.29 – 0.46	0.75
Mixed-Effects	0.34	-0.02 – 0.70	0.72	-0.15	-0.60 – 0.29	0.90
Note for dermal exposure the results are identical for each regression model indicating that ignoring MU correlations does not affect the result. See Sarkar, B., 2010 (D000000) for more information.						

Figure 6: Dermal Exposure Regression (AHETF, 2009; pg. 147)

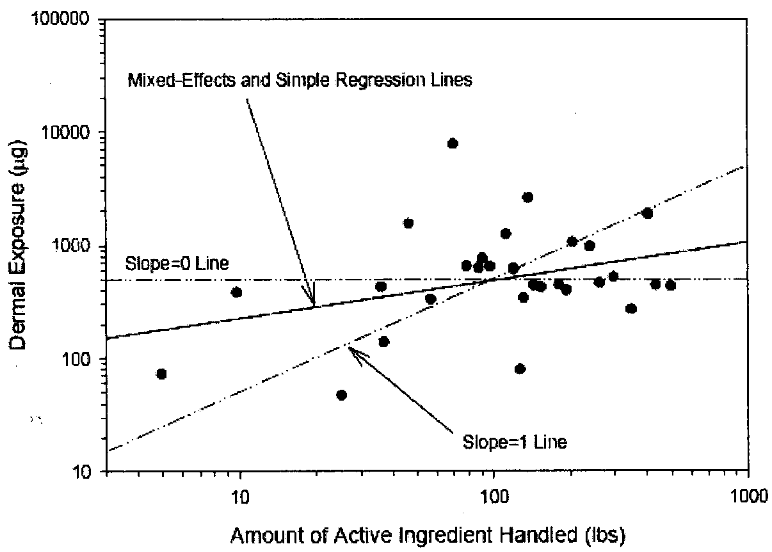
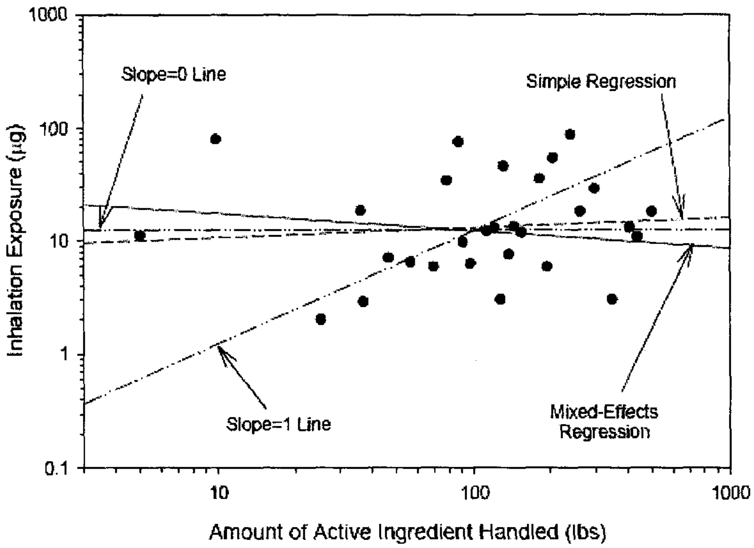


Figure 7: Inhalation Exposure Regression (AHETF, 2009; pg. 148)



The regression results show that for both dermal and inhalation exposure, the log-log regression slopes are less than 1 and the 95% confidence intervals include 0 while excluding 1, providing evidence against the default assumption of proportionality. With confidence interval widths in all cases less than 1.4, the secondary benchmark of determining proportionality or independence between exposure and AaiH with 80% statistical power was met for this scenario and the analysis confirmed independently by HED. Additionally, this objective was met regardless of whether the hand and face/neck samples were adjusted using HED's default 50% method efficiency correction.

IV CONCLUSIONS

HED has reviewed the AHETF Open Cab Ground Boom Application of Liquid Sprays monograph and concurs with the technical analysis of the data as well as the evaluation of the statistical benchmark objectives (Sarkar, B., 6/25/10; D000000). The following is a summary of our conclusions.

- Deficiencies in the existing open cab groundboom applicator PHED dataset used to calculate unit exposures have been recognized and the need for new data established.
- The AHETF data developed and outlined in the monograph and this review represent the most reliable data for assessing open cab ground boom applicator exposure.
- Though these data were developed prior to AHETF adoption of statistical analysis benchmarks, it was evaluated with respect to, and demonstrated to meet, these objectives. Estimates of the GM, AM, and P95 were shown to be accurate within 3-fold with 95% confidence and the data provided 80% statistical power to distinguish complete proportionality or independence between exposure and AaiH.
- Evidence to support independence between both dermal and inhalation exposure and the amount of active ingredient handled was found for open cab ground boom applications. As a result, HED will consider alternative uses of the data in the future, but, because it is

considered a health protective assumption, continue using exposures normalized by AaiH as a default condition.

V REFERENCES

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Hackathorn, D.R. and D.C. Eberhart. 1985. Data Base Proposal for Use in Predicting Mixer-loader-applicator Exposure. American Chemical Society Symposium Series 273, pp. 341-355.

NAFTA - Dept. of Pesticide Regulation (DPR), California EPA, HSM-98014, April 24, 1998.

Sarkar, Bayazid, 2010. Memorandum: Review of Statistical Analyses in Agricultural Handler Exposure Task Force (AHETF) Monographs. U.S. Environmental Protection Agency. June 25, 2010. D000000.

Attachment 1

AHETF Open Cab Ground Boom Applications: MU Inhalation and Dermal Exposure[a] Data Details																	
		Inhalation				Dermal											
						Field Recovery Adjusted body part-specific Residue (ug)[e]						Field Recovery Adjusted Head/Neck Residue (ug)				Total	
MU ID	AaiH (lbs)	Field Recovery Adjusted OVS Tube (ug/sample)	Avg. Pump Flow (L/min)[b]	Exposure (ug)[c]	Unit Exposure (ug/lb ai)[d]	LA	UA	FT	RT	LL	UL	Face /Neck[f]	Head[g]	Whole Head /Neck[h]	Field Recovery Adjusted Hand Residue (ug)	Exposure (ug)[i]	Unit Exposure (ug/lb ai)[j]
AHE18-A1	299	6.70	1.96	28.4	0.0949	123	22.8	48.7	47.8	34.6	48.2	61.3	37.4	98.7	91.6	515	1.7
AHE18-A2	128	0.710	1.99	2.96	0.0231	7.3	3.3	10.1	0.5	10.8	4.0	8.3	5.1	13.4	28.8	78.2	0.61
AHE20-A1	9.9	18.3	1.95	77.9	7.89	56.3	53.1	65.0	52.5	32.5	34.7	21.6	13.2	34.8	47.7	377	38.2
AHE21-A1	5	2.64	2.00	11.0	2.21	25.9	5.3	10.6	8.4	1.9	3.1	0.7	0.4	1.1	15.3	71.6	14.5
AHE21-A2	37.2	0.673	1.95	2.86	0.0770	28.9	13.8	28.7	16.1	3.4	19.7	7.2	4.4	11.6	14.4	137	3.7
AHE30-A1	25.4	0.470	1.97	1.98	0.0778	5.4	0.5	4.0	0.9	5.9	6.7	1.7	1.0	2.7	20.4	46.5	1.8
AHE30-A2	46.8	1.67	1.99	6.97	0.149	34.8	4.2	17.0	6.4	91.3	25.2	11.3	6.9	18.2	1322	1519	32.5
AHE30-A3	57	1.53	2.00	6.36	0.112	75.6	16.8	33.8	11.4	11.7	13.8	11.1	6.8	17.9	147	328	5.8
AHE30-A4	70.2	1.37	1.97	5.78	0.0823	127	17.7	39.9	9.4	23.7	31.6	134	81.7	216	7158	7623	109
AHE30-A5	91.2	2.29	1.97	9.63	0.106	95.8	15.8	24.0	9.5	37.4	18.6	236	144	380	166	747	8.2
AHE31-A1	138	1.75	1.95	7.45	0.0538	913	268	546	209	26.9	59.8	114	69.5	183	347	2553	18.4
AHE31-A2	155	2.75	1.95	11.7	0.0757	79.5	60.0	81.4	58.5	25.8	21.4	7.8	4.8	12.6	79.4	419	2.7
AHE31-A3	195	1.36	1.95	5.79	0.0296	85.3	20.6	68.6	33.7	18.0	41.9	10.5	6.4	16.9	111	396	2.0
AHE31-A4	113	2.83	1.95	12.0	0.106	252	142	173	152	17.3	56.7	82.4	50.2	133	300	1226	10.8
AHE31-A5	97.7	1.46	1.95	6.21	0.0636	124	23.6	73.3	12.6	9.8	362	10.4	6.3	16.7	17.3	639	6.5
AHE32-A1	36.4	4.38	1.99	18.3	0.502	70.9	80.6	74.7	46.1	22.4	20.3	32.7	19.9	52.6	57.3	425	11.7
AHE32-A2	408	3.05	1.96	12.9	0.0317	416	154	137	74.2	68.2	73.3	488	297	785	135	1843	4.5
AHE32-A3	350	0.721	2.01	2.98	0.00851	74.8	30.0	41.3	25.2	6.6	15.8	26.0	15.8	41.8	32.0	268	0.77
AHE32-A4	263	4.32	2.00	17.9	0.0682	64.4	29.2	30.7	24.4	26.6	39.2	35.6	21.7	57.3	185	457	1.7
AHE32-A5	88.1	18.0	2.02	74.0	0.840	61.0	33.3	80.6	22.9	58.5	85.7	70.1	42.7	113	162	617	7.0
AHE32-A6	132	10.9	2.01	45.0	0.341	19.4	49.9	41.9	19.8	67.3	12.0	49.6	30.2	79.8	46.5	336	2.5
AHE40-A1	79	7.90	1.95	33.6	0.426	137	117	142	119	7.5	22.9	30.5	18.6	49.1	46.4	641	8.1
AHE40-A2	121	3.10	2.00	12.9	0.106	79.5	26.1	93.3	37.1	50.4	243	32.3	19.7	52.0	28.7	610	5.0
AHE40-A3	145	3.12	1.95	13.3	0.0916	25.1	78.4	107	57.6	29.6	48.8	33.6	20.5	54.1	35.0	436	3.0
AHE40-A4	182	8.38	2.00	34.8	0.191	24.8	22.7	69.1	29.3	16.5	111	67.7	41.3	109	58.0	440	2.4
AHE40-A5	206	12.8	2.00	53.1	0.258	128	215	205	139	42.4	55.2	89.9	54.8	145	115	1045	5.1
AHE40-A6	241	20.2	1.95	86.0	0.356	124	145	111	194	34.4	80.3	58.0	35.4	93	175	957	4.0
AHE40-A8	438	2.57	2.00	10.7	0.0244	48.5	51.2	78.1	36.3	27.7	54.4	77.1	47.0	124	17.5	438	1.0
AHE40-A9	501	3.97	1.85	17.8	0.0355	21.1	22.7	54.1	18.7	21.9	73.1	65.6	40.0	106	111	429	0.86

[a] Dermal exposure values do not reflect default 50% adjustment to hands and face/neck measurements.
[b] Average flow rate (Start flow rate + End flow rate / 2).

[c] Inhalation Exposure (ug) = Adjusted OVS Tube Residue (ug) * [Breathing Rate (8.3 L/min) ÷ Avg. Pump Flow Rate (L/min)]
[d] Inhalation Unit Exposure = Inhalation Exposure (ug) ÷ AaiH (lbs)
[e] LA = lower arm; UA = upper arm; FT = front torso; RT = rear torso; LL = lower leg; UL = upper leg
[f] Face/neck residues are adjusted (extrapolated) to account for portions of face and neck not wiped due to PPE worn.
[g] Portion of head not measured (wiped) = PPE-adjusted face/neck residue X extrapolation ration (0.610). Based on AHETF SOP 9.K.
[h] Whole Head/Neck Residue = PPE-adjusted face/neck residue + non-wiped head residue.
[i] Total Dermal Exposure (ug) = LA + UA + FT + RT + LL + UL + Whole Head + Hands
[j] Dermal Unit Exposure (ug/lb ai) = Total Dermal Exposure (ug) ÷ AaiH (lbs)

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Chemical Name:	
PC Code:	
HED File Code:	**12000 Exposure Reviews**
Memo Date:	**3/11/2011**
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